



OCT 9 0 2007

PREMARKET NOTIFICATION 510 (k) Summary

As required by 21 CFR 807.92

Device name – as required by 807.92(a)(2):

Trade Name: Faxitron MX-20 Specimen Radiography System

Common/Classification Name: Specimen x-ray System/Cabinet X-ray System

Classification Regulation: 21 CFR 892.1680

Device Class: Class II

Product Code (Procode): MWP

Panel: Radiologic Devices Panel

Premarket Notification submitter:

Company Name: Faxitron X-ray Corporation

Company Address: 225 Larkin Drive, Suite 1
Wheeling, IL 60090-7209

Contact: Douglas C. Wiegman,
VP Engineering and Regulatory Affairs

Preparation Date: September 6, 2007

A. LEGALLY MARKETED PREDICATE DEVICES – as required by 21 CFR 807.92(a)(3)

The Faxitron MX-20 Digital Specimen Radiography System is substantially equivalent to the following to the following predicate devices:

- o Faxitron Micro 50 Specimen Radiography System-K852634
- o Faxitron DX-50 Digital Radiography System-K061361

- piXarray Digital Specimen Radiography System-K052433

B. DEVICE DESCRIPTION – as required by 21 CFR 807.92(a)(4)

The Faxitron MX-20 Specimen Radiography System is a Cabinet X-ray System specifically designed to provide high detail radiographic imaging of surgically excised medical specimens. The exceptionally high magnification capability (up to 5X) from the 0.02 mm focal spot with optimized cabinet geometry and the superior contrast available from the low kV capability provides enhanced film and/or digital imaging performance. This device supports radiographic film sizes up to 30 x 35 cm and can be configured to acquire high resolution, DICOM compliant, digital x-ray images through the use of an integrated camera and Faxitron Specimen Radiography software.

C. DEVICE CLAIMS – as required by 807.92(a)

The Faxitron MX-20 Specimen Radiography System is a fully shielded Cabinet X-ray System that has been designed to comply with 21 CFR 1020.40. The system allows up to 5 times geometric magnification of excised specimens with minimal geometric distortion through the use of a focal spot size that is less than 20 microns. The x-ray coverage of the device allows the use of radiographic film sizes up to 30 x 35 cm. The device can also be configured to provide high resolution, DICOM compliant, digital images through the use of an integrated digital camera and Faxitron Specimen Radiography software. The Faxitron Software supports the DICOM Store, Print and Modality Worklist services.

D. DEVICE TECHNICAL SPECIFICATIONS – as required by 807.92(a)(4)

Cabinet Specifications:

- Energy Range: 10-35 kV
- Tube Current: 300 μ A
- Focal Spot Size: < 20 microns
- Window Filtration: 0.03"
- X-ray Coverage: 30 x 35 cm
- Power: 100-240 VAC, 50/60 Hz, 150VA
- Dimensions:
 - External: 17" W x 18.5" D x 29" H
 - Internal: 14" W x 16" D x 19" H
- Weight: 150 lbs.

Digital System Specifications:

- Active image Area: 12 x 12 cm
 - Options: 5 x 5 cm or 5x 10 cm
- Typical Spatial resolution: 10 lp/mm

- DICOM 3.0 compliant software includes Store, Print and Modality Worklist
- Network ready workstation and monitor included

E. INTENDED USE – as required by 807.92(a)(5)

Indications for Use: The MX-20 is a Cabinet x-ray system that is used to provide film and/or digital x-ray images of harvested specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

Doing the verification directly in the same room or nearby enables cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls.

F. LEVEL OF CONCERN – as required by recent FDA guidance

Faxitron has determined that the submitted device has a “**moderate**” software **Level of Concern** and has provided that documented record as part of this submission.

G. TECHNOLOGICAL CHARACTERISTICS SUMMARY

The MX-20 Specimen Radiography System has the same indications for use as the predicate devices listed above. The technological characteristics of the MX-20 Specimen Radiography System have been compared to the predicate devices sited and is covered in detail in the Substantial Equivalence section of this submission. Differences in the MX-20 Specimen Radiography system as compared to the predicate devices sited are summarized in the table below.

TABLE OF DIFFERENCES BETWEEN THE MX-20 SPECIMEN RADIOGRAPHY SYSTEM AND THE PREDICATE DEVICES SITED

Characteristic	Faxitron MX-20	Faxitron Micro 50	Faxitron DX-50	Bioptrix piXiarray
Energy range	10 – 35 kV	15 – 50 kV	10 – 35 kV	5- 45 kV
Tube current	0.3 mA	0.35 mA	0.1 mA	0.5 mA
X-ray Coverage	41.6 cm	25 cm	14.6 cm	19 cm
Focal Spot Size	< 20 microns	50 microns	50 microns	50 microns
Magnification Capability	Up to 5 times	Up to 2 times	Up to 1.5 times	Up to 1.4 times

As can be seen from the Table above the energy ranges for the MX-20 Specimen Radiography System and the predicate devices listed are very similar. One advantage that the MX-20 Specimen Radiography System has over the predicate devices is the size of the focal spot and the geometric magnification capability of the device. In addition the MX-20 Specimen Radiography Systems uses the same digital imaging hardware and software as the Faxitron DX-50 Digital Radiography System.

H. NONCLINICAL PERFORMANCE DATA TESTING AND REVIEW – as required by 807.92(b)(1)

The MX-20 Specimen Radiography System is a Cabinet X-ray System and has been designed and tested to comply with the performance standards set forth in 21 CFR 1020.40 Cabinet X-ray Systems. Testing and performance data pertaining to this standard has been included as part of the submission. This device has also been tested for electrical safety and is Classified by Underwriters Laboratories in the US and Canada. Additional testing to certify compliance to the European Low voltage and EMC directives has been successfully completed and documented in this submission.

I. Substantial Equivalence Summary

The MX-20 Specimen Radiography System has the same indications for use as the predicate devices sited. The technical characteristics of the MX-20 are very similar to the predicate devices. One major difference that we believe allows the MX-20 Specimen Radiography System to perform better than the predicate devices sited is the size of the focal spot (<20 microns) and the optimized cabinet geometry which allows greater x-ray coverage and higher geometric magnification of excised specimens with minimal geometric distortion.

J. CONCLUSIONS

We conclude that the documentation and testing included in this submission indicates that the MX-20 Specimen Radiography System is safe and effective and substantially equivalent to the predicate devices sited.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 2007

Mr. Douglas C. Wiegman
VP Engineering
Faxitron X-ray Corporation
225 Larkin Drive, Suite 1
WHEELING IL 60090-7209

Re: K072557

Trade/Device Name: MX-20 Specimen Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MWP
Dated: September 6, 2007
Received: September 11, 2007

Dear Mr. Wiegman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(K) Number (if known): K072557

Device Name: **MX-20 Specimen Radiography System**

Indications for Use: The MX-20 is a Cabinet x-ray system that is used to provide film and/or digital x-ray images of harvested specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)